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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/730,380	12/05/2000	Ken Liljegren	5432/01004	7399

7590 05/23/2006

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805 Third Avenue  
New York, NY 10022

EXAMINER
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AULAKH, CHARANJIT

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/730,380	LILJEGREN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Charanjit S. Aulakh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,4-10,12,13 and 36-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-10,12,13 and 36-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1 page</u> . | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1625

### DETAILED ACTION

1. According to paper filed on Aug. 9, 2005, the applicants have filed a RCE of allowed application.
2. Claims 1, 4-10, 12, 13 and 36-43 are now pending in the application.

### ***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 4-10, 12, 13 and 36-43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 26-47 of U.S. Patent No. 6,916,941. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant tablet prepared by direct compression of crystals of a pharmaceutically acceptable salt of citalopram having median particle size of crystals of at least 40 um encompasses the tablet prepared by

Art Unit: 1625

direct compression of crystals of escitalopram oxalate having median particle size of crystals of atleast 40 um claimed in the cited patent.

5. Claims 1, 4-10, 12, 13 and 36-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 and 13-15 of copending Application No. 10/310,621. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application differ from the claims of the cited application in preparing a tablet of crystals of pharmaceutically acceptable salts of citalopram. However, the median particle size of crystals is identical in the instant application and the cited application and therefore, preparing unit dosage in the form of a tablet is within the routine skill of a pharmacist or an artisan in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1, 4-10, 12, 13 and 36-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 11/238,517. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application differ from the claims of the cited application in preparing a tablet by direct compression instead of a pharmaceutical product of crystals of pharmaceutically acceptable salts of citalopram. However, the median particle size of crystals is identical in the instant application and the cited application and therefore, preparing unit dosage in the form of a tablet is within the routine skill of a pharmacist or an artisan in the art.

Art Unit: 1625

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1, 4-10, 12, 13 and 36-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-19, 34 and 35 of copending Application No. 10/966,725. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application differ from the claims of the cited application in preparing a tablet of crystals of pharmaceutically acceptable salts of citalopram. However, the median particle size of crystals is identical in the instant application and the cited application and therefore, preparing unit dosage in the form of a tablet is within the routine skill of a pharmacist or an artisan in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1, 4-10, 12, 13 and 36-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 52-63 and 88 of copending Application No. 11/053,641. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant tablet prepared by direct compression of crystals of a pharmaceutically acceptable salt of citalopram having median particle size of crystals of at least 40 um encompasses the tablet prepared by direct compression of crystals of escitalopram oxalate having median particle size of crystals of at least 40 um claimed in the cited application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


9. Claims 1, 4-10, 12, 13 and 36-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 and 40-52 of copending Application No. 10/851,763. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application differ from the claims of the cited application in preparing a tablet of crystals of escitalopram oxalate. However, the median particle size of crystals is identical in the instant application and the cited application and therefore, preparing unit dosage in the form of a tablet is within the routine skill of a pharmacist or an artisan in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on (571)272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Charanjit S. Aulakh  
Primary Examiner  
Art Unit 1625